STUDY TITLE

Implementing and evaluating a weight reduction program for Diabetic patients at a Primary Health Care Facility in the Western Cape.

INVESTIGATORS

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March 2016

DECLARATION

I, Dr A Razack……., hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Index:

Abstract:

Background:

Diabetes is now the most common non-communicable disease globally and complications are resulting in increased disability, reduced life expectancy and enormous health costs for virtually every society. Medical Nutrition Therapy is important for the prevention, treatment, self-management of diabetes and the prevention or delay in onset of diabetes-related complications. The current nutritional guidelines for DM states that carbohydrates should make up 45-60% of the total nutritional intake and that low carbohydrate or high protein diets offer no long term success over healthy eating plans. Recent studies suggest that there may be merit in using low carbohydrate diets in diabetic patients.

Aim and Objectives:

The study aimed to implement and evaluate a program for weight loss in Diabetes Mellitus type 2 patients by comparing a Low carbohydrate diet to the conventional low fat diet. Changes in weight, waist circumference, blood pressure and blood parameters (creatinine, lipids and HbA1c) were recorded in both groups.

Methods:

The study design was that of a two group randomised parallel design, with one group following a low fat diet and the other a low carbohydrate diet. Both groups received advice on exercise and behaviour change. Clinical parameters were recorded at week 0 (baseline) and week 12 of the program. Patients were invited to participate in the study using leaflets, posters and via staff. A total of 10 patients per group were identified and followed.

Results:

Significant reductions were seen in weight loss and Hba1c in the Low Carbohydrate diet group which was not evident in the Low fat diet group. No significant change was seen in other parameters including BP, total cholesterol and serum creatinine for either group.

Conclusion:

Low Carbohydrate diets are effective in promoting weight loss and glucose control in diabetic patients. More research is recommended to assess patient's experience of following a low carbohydrate diet. Recommendations include training staff at facilities in our Sub-District on understanding and implementing Low Carbohydrate diets.

List of Abbreviations:

BMI = Body mass index

BP = Blood pressure

CHC = Community health care centre

DM = Diabetes Mellitus

LC = Low carbohydrate

LF= Low fat

MNT = Medical nutritional therapy

PHC = Public health care centre

SEMDSA = Society for endocrinology, metabolism and diabetes South Africa

Introduction:

The incidence of diabetes mellitus type 2 (DM 2) and its subsequent complications are on the rise[1]. The Diabetic Atlas[1] states that diabetes is now the most common non-communicable disease globally and complications are resulting in increased disability, reduced life expectancy and enormous health costs for virtually every society. It also states that globally 382 million people have diabetes and that this will rise to 592 million by 2035[1]. In South Africa the comparative prevalence for diabetes is 9.27 %.[1]A study done in Bellville, Cape Town between 2008 and 2009 showed that the prevalence of DM 2 increased hugely in the coloured community (28.2% compared to previous study in 1999 showing 7.1%)[2].

The South African National Health and Nutrition Examination Survey found that in 2012 the prevalence of overweight and obesity was significantly higher in females than males (24.8% and 39.2% compared to 20.1% and 10.6% for females and males, respectively) [3.] It also found that the Western Cape was one of four provinces with significantly higher HBa1c values (>6%) and this value was higher within the Coloured and Asian/Indian population.[3] Raised Hba1c values amongst coloured diabetics were further supported by data from the 2013 chronic disease audit of Mitchells Plain CHC[4.] This audit showed that, of the recorded Hba1c (60 % of the sample), all were over 7, this despite 70% of the sample being educated regarding diet and exercise.

According to Dr Bob Mash [5], diabetes is a chronic, manageable condition which requires major changes in lifestyle to optimize its management. The current SEMDSA guidelines[5] states that Medical Nutrition Therapy (MNT) is important for the prevention, treatment, self-management of diabetes, and the prevention or delay in onset of diabetes-related complications. MNT can reduce HbA1c by 1-2%, depending on the duration of diabetes.

The current nutritional guidelines for DM states that carbohydrates should make up 45-60% of the total nutritional intake and that low carbohydrate or high protein diets offer no long term success over healthy eating plans.[5] Recent studies discussed in the literature review suggest that there may be merit in applying low carbohydrate diet plan in diabetic patients.

Literature review

A two year randomised control trial done in Israel (2008)[6] compared weight loss with a low carbohydrate diet to a Mediterranean or low fat diet amongst 322 participants.[6] The Mediterranean-diet group consumed the largest amounts of dietary fibre and had the highest ratio of monounsaturated to saturated fats; the low-carbohydrate group consumed the smallest amount of carbohydrates and the largest amounts of fat, protein and cholesterol. The study concluded that Mediterranean and low carbohydrate diets are safe and may be effective alternatives to weight loss compared to low-fat diets. The mean weight loss was 2.9kg for the low fat groups, 4.4 kg for the Mediterranean group and 4.7kg for the low-carbohydrate group. A study done in Philadelphia (2004) randomly placed 132 severely obese subjects (39 % diabetic) on either a low carbohydrate or low fat, calorie restricted diet.[7] Seventy nine subjects completed the six month study. The results showed that subjects on the low carbohydrate diet lost more weight than the low fat diet group (mean weight loss 5.8 kg vs. 1.9 kg p = 0.002). Insulin sensitivity, measured only on non-diabetic subjects, also showed better improvement as did triglyceride levels in the low carbohydrate group.

To address the concern of high protein diets on the kidney, a two year randomised control trail was carried out between 2003 and 2007 in three medical centres in the USA[8]. A total of 307 obese (BMI 30-40) adults were recruited and randomly assigned to one of the two diets and followed up for 3, 12 and 24 months. Results showed that the low carbohydrate diet was associated with reductions in serum creatinine and cystanin and relative increases in creatinine clearance, serum urea and 24 hour urinary volume. It concluded that in healthy obese individuals, a low-carbohydrate high-protein weight-loss diet over 2 years was not associated with noticeably harmful effects on GFR, albuminuria, or fluid and electrolyte balance compared with a low-fat diet.

A recent study compared traditional high fibre weight-loss (50% carbohydrate, 20 % protein) diets to relatively high protein (30% protein 40% carbohydrate) weight loss diet in overweight or obese woman[9]. Eighty three woman aged between 18-65 years and with a BMI of >27 were randomised into the high fibre/ high carbohydrate group or high protein (HP) group and followed for eight weeks. Energy intakes were reduced in both groups by 2000 to 4000 KJ per day in-order to achieve weight loss. Results showed that both groups achieved weight loss, reduced body fat, reduced weight circumference and reduced total cholesterol, LDL and TG. Both groups also showed improvement in blood pressure and fasting plasma glucose. The HP group however showed better results in all of the above parameters.

A review article published in 2005 looked at evidence from various randomized controlled trials regarding safety and efficacy of low carbohydrate diets for diabetic patients.[10] They stated that such diets are safe and effective. They can be comparable or better than traditional low fat carbohydrate diets in reducing weight, improving dyslipidaemia, reducing blood pressure, reducing triglycerides and increasing HDL.

A systematic review and meta-analysis of clinical trials of the effects of low carbohydrate diets (LCD) on cardiovascular risk factors was published in 2012[11]. It reviewed a total of 23 reports corresponding to 17 clinical investigations. Meta-analysis carried out on data obtained in 1,141

obese patients, showed that LCD to be associated with significant decrease in body weight, BMI, abdominal circumference, systolic blood pressure, diastolic blood pressure, plasma triglycerides, fasting plasma glucose, HBa1c, plasma insulin and plasma C-reactive protein and an increase in HDL cholesterol.

Low-fat dairy products form part of the traditional medical nutritional therapy as stated by SEMDSA.[5] Published in the European nutritional journal in 2012 was a systematic review of observational studies on relationships between diary fat and high fat dairy foods, obesity and cardiovascular risks.[12] They integrated their findings with data from controlled studies showing effects of several minor diary fatty acids on adiposity and cardio/metabolic risks. Results showed that in 11 of the 16 studies high fat intake was inversely associated with measures of adiposity. The review concluded that evidence does not support the hypothesis that diary fat or high fat dairy foods contribute to obesity or cardiovascular risk.

A twelve month randomised control trial done in the USA between February 2003 compared 4 popular weight loss diets among 311 free living overweight or obese(BMI 27-40), non-diabetic premenopausal woman.[13] The four diets were known as the Atkins (high protein/ low carbohydrate), Zone (40% carbohydrate, 30% protein, 30% fat), LEARN (prudent diet 60 % carbohydrate) and Ornish (10% fat)diets. Primary outcome was weight loss and secondary outcomes were, among others, lipid profile and blood pressure. The results showed that mean weight loss was significantly higher in the Atkins group (-4.7 kg compared to LEARN -2,7 kg, Ornish -2.2kg, Zone 1.6kg). The study concluded that low carbohydrate, high protein, high fat diets may be a feasible alternative to conventional weight loss strategies.

In 2003 a Randomised Control trial was done in Cincinnati, USA. The effects of a very low carbohydrate diet as compared to a calorie restricted diet on cardiovascular risk factors were tested[14]. A total of 53 women were included based on criteria including BMI between 30-35 and age above 18 years. Weight loss as well as blood pressure, lipids, fasting glucose and insulin were measured after three and six months. The very low carbohydrate group showed a greater loss of weight at a mean weight loss of 8.5 kg (p= < .001). Mean blood pressure, lipids, fasting glucose and insulin were at normal values at the beginning of the trial and improved in both groups with no significant differences.

In 2004 a trial approved by the Mount Sinai Medical centre in the USA compared a National cholesterol education program diet to a diet lower in carbohydrates and higher in protein and monosaturated fats[15]. This randomised control trial included 60 male participants aged 28-71 and with BMI's of >27. They were followed up every 2 weeks and the trial lasted for a total of 12 weeks. Primary outcomes were weight loss while secondary outcomes included blood lipid levels. Results of the trial showed that the low carbohydrate group lost more weight (13.6 lb/6.2kg) compared to the national cholesterol education program diet group (7.5lb/3.4kg). Favourable blood lipid changes were also noted in the low carbohydrate group.

More recently a systematic review and meta-analysis published in Plos One 2014 compared low carbohydrate with isoenergetic balanced diets for reducing weight and cardiovascular risk[16]. This study reviewed randomised control trials (parallel or crossover) where the two diets were implemented among overweight and obese adults for a minimum of 12 weeks. Outcomes measured included BMI, BP, LDL, HDL, TG,Hba1c. The study showed that among type 2 DM patients little differences were found with respect to weight loss, cardiovascular risk and glycaemic control.

A randomised parallel group trial was carried out at the Tulane University Health Sciences Centre in New Orleans during 2008 and 2011[17]. A low carbohydrate diet (< 40g total carbohydrate minus fibre) was compared to low fat diet (< 30% fat of total energy intake) among a total of 148 participants. Patients were followed up over a 12 month period. Neither diet included a specific calorie or energy goal. Results showed that after 12 months the low carbohydrate group had greater reduction in weight (P= 0.002), fat mass (P=0.011), Triglyceride level, (p=.038) and had greater increases in HDL (P<0.001).

Aim and objectives:

Aim:

The study aimed to implement and evaluate a program for weight loss in DM 2 patients.

Objectives:

1. Implement a weight loss program for DM 2 patients in two parallel patient groups. One group received the low carbohydrate diet (Addendum 1) while the other a conventional low fat diabetic diet (addendum 2).
2. Measure effects of program on changes in weight, waist circumference, blood pressure and blood parameters (creatinine, lipids and BbA1c) on both groups.
3. Make recommendations for implementation at other PHC facilities.

Study design:

The study design was that of a two group randomised parallel design.

Setting:

The study was done at Mitchells Plain CHC within the chronic club unit between Jan 2013 and Dec 2015.

Sampling:

Overweight or obese (BMI >25) DM type two patients attending the Mitchells Plain CHC were invited to participate in the program.

The inclusion criteria were as follows:

- DM 2 patients for at least 1 year
- Age 18-65 years
- BMI >25
- Ability to attend clinics for follow up
- Adherent to current medications (was checked from attendance rates, interviews)

Exclusion criteria were similar to studies discussed in the literature review. (The Mediterranean study in Israel[6] and 2004 Philadelphia study[7])i.e.

- Pregnancy/ lactation
- Abnormal serum creatinine (>90 umol/l)
- Sever dyslipidaemia (>7.5mmol/l)
- Liver disease (Increased ALT)
- Malignancy
- GIT abnormalities (e.g.,Inflammatory Bowel disease, Peptic Ulcer disease)
- Currently on another trial or weight loss program

Methods

Patients were invited to participate in the study using leaflets, posters and via staff. The first 20 patients who fit the inclusion criteria were assigned to the low carbohydrate group and initiated on the diet program (group1). A comparison group was then later identified and initiated on the low fat diet (group2).All consented to the diet and investigations and signed the consent form (addendum4).

Sample Size

The Mount Sinai study[15] done in 2004 used a total of 60 males while the study done in Cincinnati USA[14], used 53 females. Due to our limited time and recourses we proposed a sample size of between 15-20 participants per group. This number proved hard to achieve. Although more than 20 patients were initially recruited only half could be followed up per group. Reasons for this included:

- Loss of interest in the study
- Transport
- Unable to contact patients (address/phone number changed)
- Time period and researchers were limited

Both groups received education regarding the proposed diet. Education sessions however, had to be reduced in-order to accommodate patients. All patients in each group received at least two sessions and a final follow up session. The time period from the first session to the last was 12 weeks for both groups. All sessions were given by Dr Razack. Group 1 consisted only of females while group 2 had only two males among 8 females. Average age of group 1 was 49.2 (min 42 max 66) Average age of group 2 was 49.6 (min 35 max 59).

Session 1:

- Diets explained to participants
- Answer questions and concerns about diets
- Motivational talk to mentally prepare for change
- Introduce 3 simple exercises (10-15 min) to be done 4 times a week (addendum 3)
- Initial parameters and bloods taken (if bloods were taken within last 6 months they were used to save costs)

- Consent signed
- Diet implemented

Session 2:

- Check understanding of diets
- Continue motivation for change

Session 3:

- Discussion of results and feedback from patients and staff.

Initial baseline parameters recorded at week 0 and week 12:

- Weight/ BMI
- Blood pressure
- HBa1c
- Serum Creatinine
- Total cholesterol
- Waist circumference

6. Ethical considerations and reporting of results

Ethical oversight for the study was obtained from the Ethics and Research Committee, Faculty of Health Sciences of the University of Cape Town. Approval for the study was obtained from the Provincial Research Committee, director of the Sub-Structures as well as from the facility manager of Mitchells Plain CHC. Individual patients signed consent and confidentiality was maintained by the researchers. There is no conflict of interest for any of the research investigators.

Consideration of Beneficence:

The aim of the study is to implement a weight loss strategy that could assist and improve quality of life for each of the participants and subsequently reduce risk for complications of diabetes. If successful the strategy could be implemented at other CHC's thus improving outcomes for a greater population and reducing the burden of disease.

Consideration of potential harm:

Some concerns were raised regarding weight loss through ketosis and the effect of a higher protein diet on renal functions[8]. The literature does not support any significant dangers of a LCD. During the study period no patient showed any signs of deteriorating health. One group 2 patient showed worsening renal function that was appropriately managed and referred.

Cost:

Was not applicable as policy of the CHC dictates that Hba1c, Cholesterol, Creatine bloods should be done 6 monthly if stable or 3 monthly if not. Additional costs like printing and transport were covered personally.

Results: (Group1=LCH, Group 2= LF)

Table 1: Comparison of indicators for the diets at week 0 and week 12:

	Group1 (Low Carbohydrate Diet)						Group 2 (Low Fat diet)					
	Mean W 0	Mean W 12	Mean change	SD W0	SDw12	**p-value**	Mean w 0	Mean w 12	Mean change	SD W0	SD W12	**P-Value**
WT (Kg)	114,6	112,75	-1.85	21.3	20.46	0.037	87	87,1	+.1	10.6	10.4	0.81
WC (cm)	129,2	128,3	-0.9	10.8	9.42	0.31	106	106,2	+.2	7.37	6.61	0.37
BMI	45,6	44,9	-0.7	7.79	7.68	0.132	33,1	33,2	-0.1	3.70	3.66	0.34
DBP (mm/ mg)	78.4	84.4	-6	9.24	5.92	0.076	78.5	73.5	5	8.69	12.3	0.19
HbA1C %	10,84	9,12	-1.72	2.417	2.42	0.006	9,93	9,61	-0.32	1.71	1.94	0.558
CR(um mol/l)	59,2	60,8	+1.6	18.01	21.27	0.75	66	65,3	-0.7	16.03	26.39	0.86
CHOL (mmol /l)	4,97	4,66	-0.31	1.08	1.02	0.38	4,88	4,8	0.08	1.77	1.49	0.79

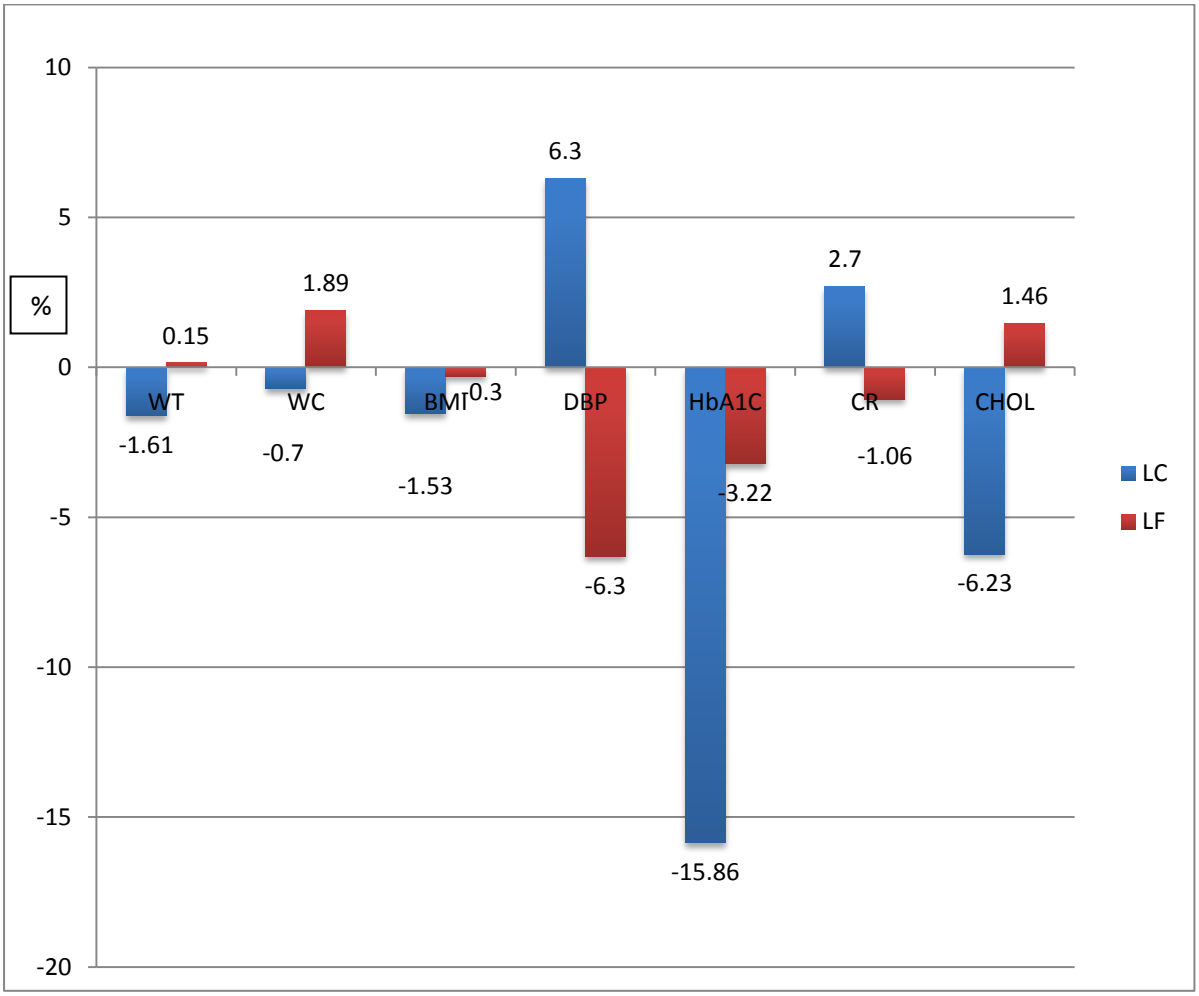

Figure 1: The percentage change after week 12 for the various indicators.

Weight:

At week 0 average weights differed from 114,6kg in the LCH group and 87kg in the LF group. SD was larger in the LCH group showing more variable weights. At week 12 the LCH group showed a statistically significant average weight loss of 1.85 kg (p=0.03) compared to the LF group showing a average weight gain of 0 .1 kg (p=0.8). The largest weigh loss in the LCH group was 6kg compared to 2 kg in the LF group.

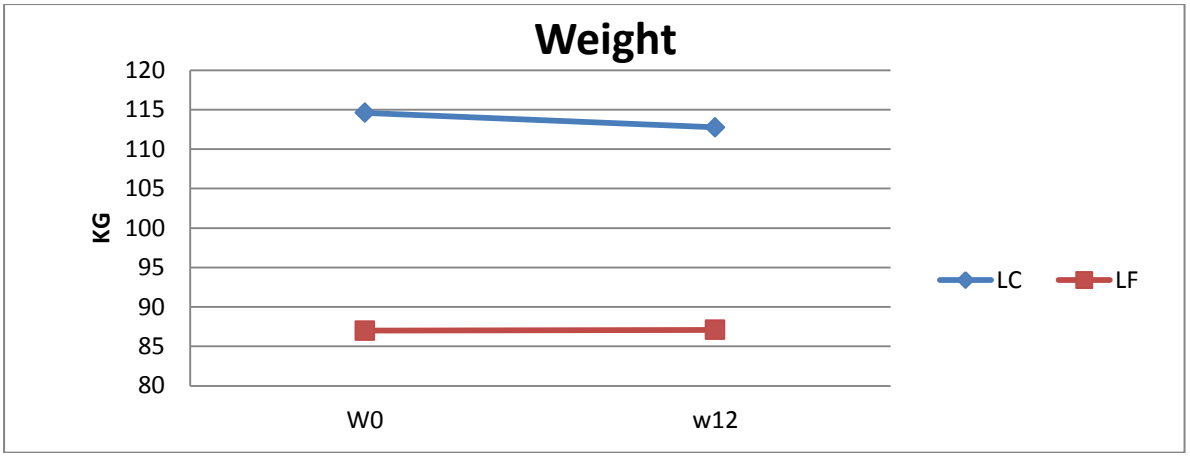

Figure 2: Difference in mean weight over 12 weeks.

Waist circumference:

An average reduction in waist circumference in the LCH group was 0,9 cm compared to an increase of 0.2cm in the LF group. These results however were not statistically significant with p=0.3 in group 1 compared to P= 0.7 in group 2.

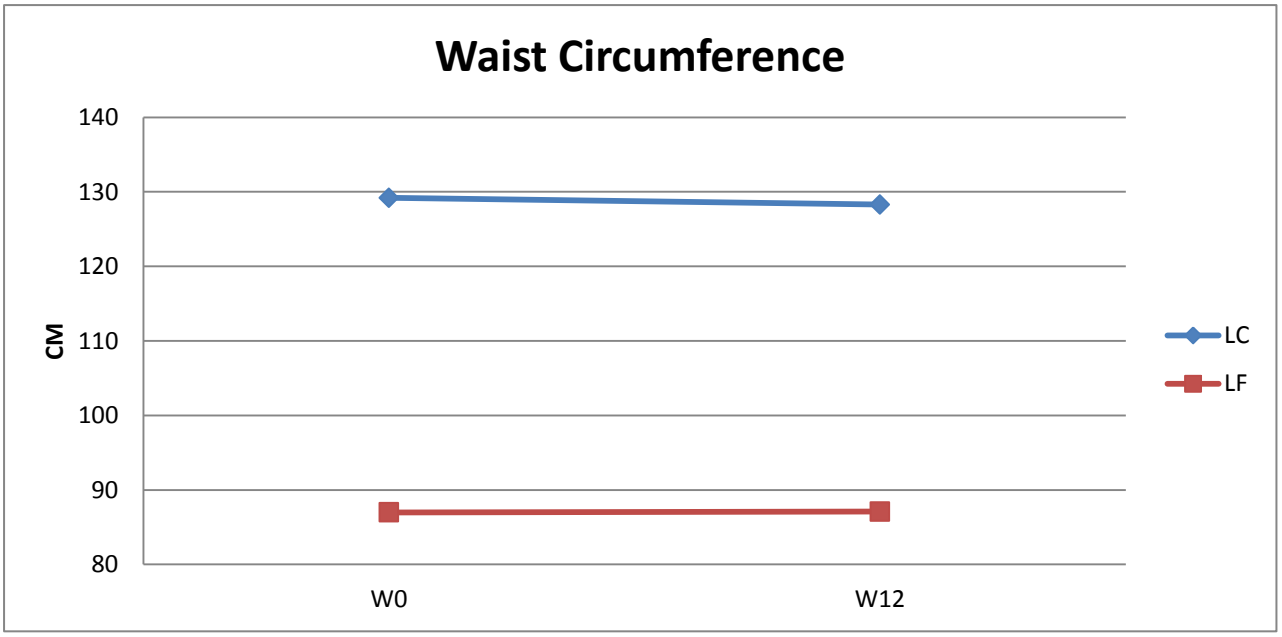

Figure 3: Difference in Mean waist circumference over 12 weeks.

BMI:

Average BMI depicted a fall in the LCH group of 0 .7 compared to 0.1 in the LF group. This was not statistically significant with P= 0.132 in group1 compared to 0.34.

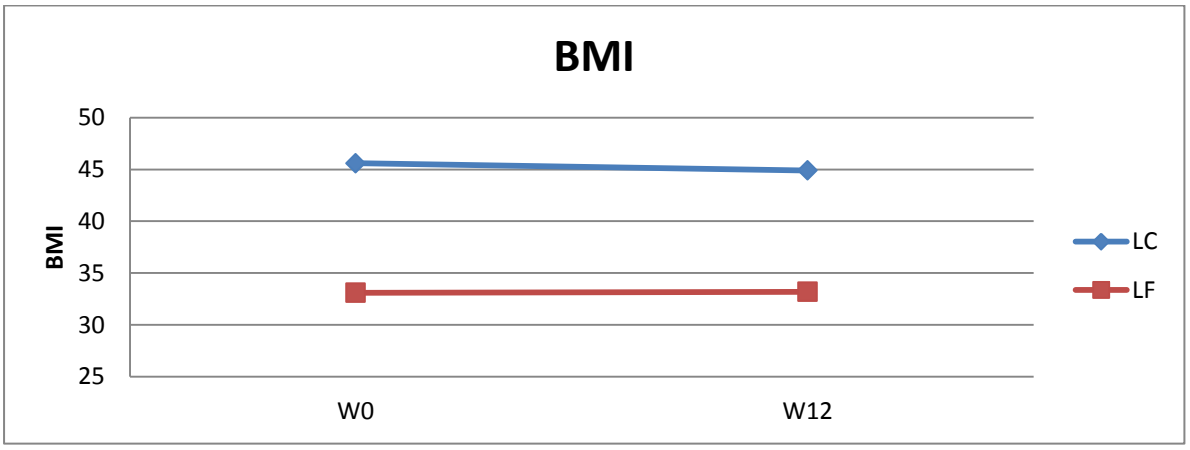

Figure 4. Differences in mean BMI over 12 weeks

BP:

According to JEMDSA the systolic target of 130 mmHg in type 2 DM has always been an extrapolated one with no direct evidence of benefit from randomised trials[5]. It was therefore decided to focus on changes in diastolic BP. Group one showed an Increase in DBP while group2 a decline. This increase was in the normal range. None of the values showed significance with a P value of 0.076 in group 1 and 0.19 group 2.

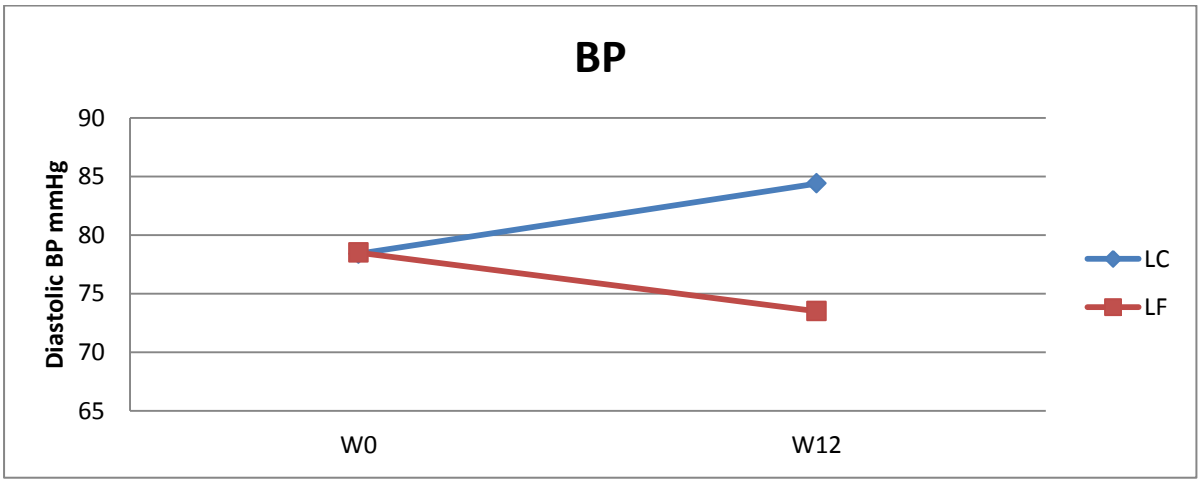

Figure5. Changes in mean diastolic Bp over 12 weeks

Hba1c:

At week 0 average Hba1c was 10.84 in group 1 compared to 9.93 in group 2. Baseline variables differed only slightly between groups with SD of 0.76 in group1 and 0.54 in group two. At week 12 Hba1c fell by 1.72 in group 1 as opposed to 0 .32 in the group 2. The results in group one wasstatistically significant with a p value of 0.006, this was not reflected in group 2 with p=0.55.

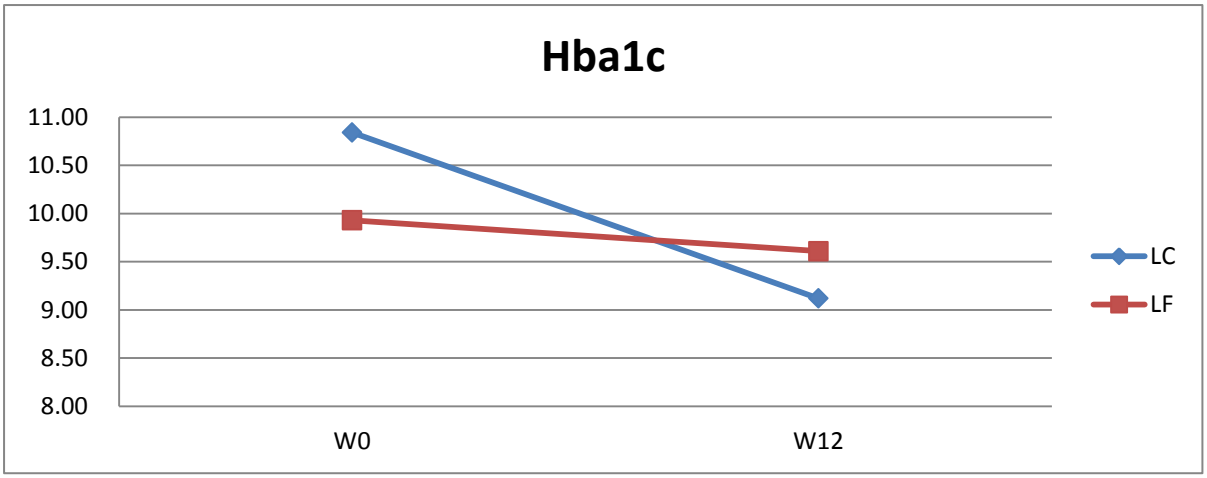

Figure 6. Difference in mean Hba1c over 12 weeks

Creatinine:

Cr remained stable except for one patient in the LF group showing a jump to 118. Differences in average values were not statistically significant in both groups with P=0.75 in group1 and P=0.86 in group 2.

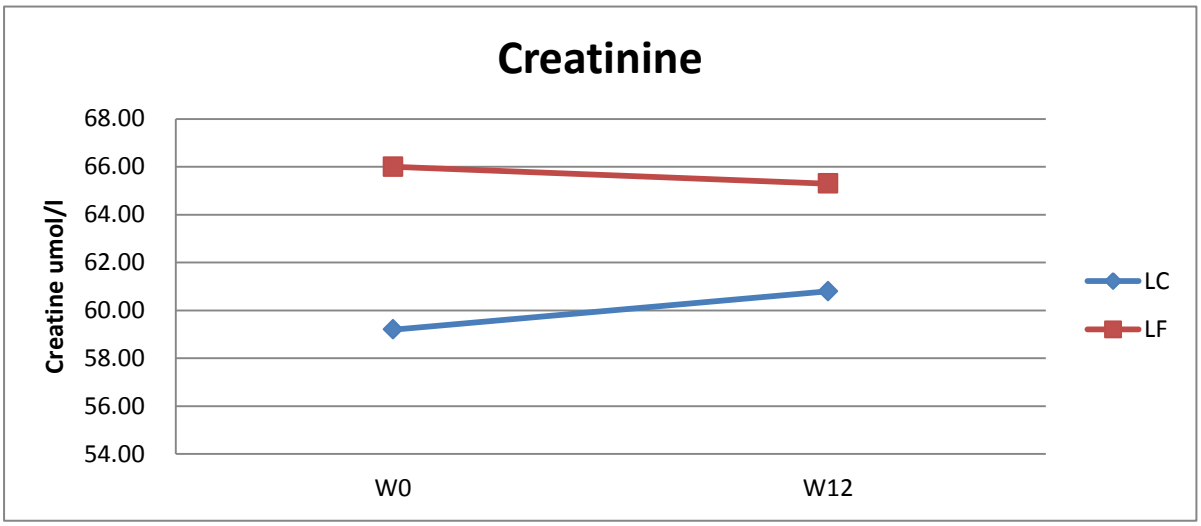

Figure 7.Difference in mean Creatinine over 12 weeks.

Cholesterol:

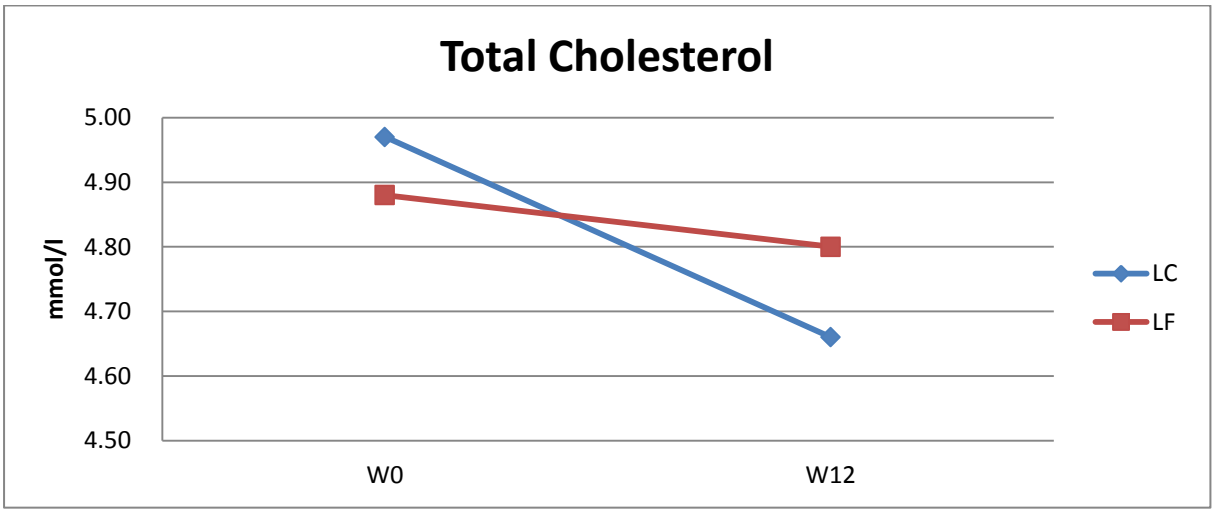

Figure 8: Differences in mean total cholesterol over 12 weeks.

Tot Cholesterol showed little difference between the two groups and between w0 and 12. This was reflected with P values of 0.38 and 0.79 respectively.

Discussion

Despite small sample size some indicators, perhaps the most important ones showed significant change (weight and Hba1c). Hba1c remains an important predictive factor in prognosis for diabetic patients[5]. Insignificant changes to BP, Cholesterol and Creatinine were welcomed as these were stable at the beginning of the study. The 2003 Randomised Control trial done in Cincinnati, USA[14,] and the Tulane University Health Sciences showed similar significant results with regards to weight loss[17].

The major weakness of the study was the small sample size. As mentioned before, time and staff were limited. Patients, mainly female, had many responsibilities preventing them from following up. In the Low fat group, patients seemed to lack motivation as the diet proposed was already something they knew and felt will not work. This was a confounding factor. Much care was taken to motivate both diets similarly but the LCH diet seemed more novel and allowed patients a newer approach to weight loss. Although patients verbally confirmed that they followed the diets, we could not guarantee or measure that they followed diet guidelines closely.

Important questions remain around the cost and convenience of low carb diets. Cost may be balanced by using cheaper proteins like beans and aval. Rawer and natural ways of eating could also be cheaper than processed foods. The notion also exists that over time hunger and cravings will subside and patients will, as a whole, consume less and thus spend the same amount of money. Needless to say, the long term implications from less diabetic related complications could benefit patients and decrease government expenditure. Further research is needed to quantify such benefits as well as qualitative aspects of adhering to the diet over a longer period.

Recommendations include training staff at facilities in our Sub-District on understanding and implementing LC diets, larger studies involving more facilities and using patients who have benefited from the diet to share their successes with other.

Conclusion:

Many arguments and discussions still exist as to which diet is best. The current evidence favours the LC diets for weight loss and improving cardiovascular risk factors. Patients are frustrated as to the best diet to follow since they are receiving conflicting information from health care workers. Until definitive research exists proving one diet better than the other, the very least we should offer is a choice. Results from this study as well as from studies discussed in the literature reviews should deem it safe to offer patients a low carb option to optimise the nutritional aspect of diabetic care. Common sense and individual enquiry should never be replaced by written and prescribed diets. Needless to say the role of a good family clinician is paramount in the health and risk profile of diabetic patients.

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Addendum 1
Simple low carbohydrate diet plan[18]:

The main aim of the diet is to reduce carbohydrate intake and supplement it with larger quantities of protein and vegetables.

1) Avoid "white" carbohydrates
    a. All breads (including brown) and cereal
    b. Roti, pasta and tortillas
    c. All rice
    d. All fried food with breading/crumbs
    e. Potatoes, sweet potatoes.

2) What to eat:

    a. Proteins
        i. Eggs, chicken, beef, lamb, mutton, fish, pork
    b. Legumes
        i. Lentils, beans, "daal"
    c. Vegetables
    d. all except those listed above

    No restrictions on food listed above

3) Avoid carbohydrate rich drinks-all gas drinks

    a. Drink tea/coffee with no sugar (substitute with cinnamon)
    b. Limit aspartame "zero" drinks
    c. Red wine permissible in moderation

4) Avoid fruits
5) Eat meals +- 4 hrs apart

Snacks: Yogurt, Nuts, Biltong

Addendum 2.2 Simple low fat eating plan (Adapted from DMSA)[19]

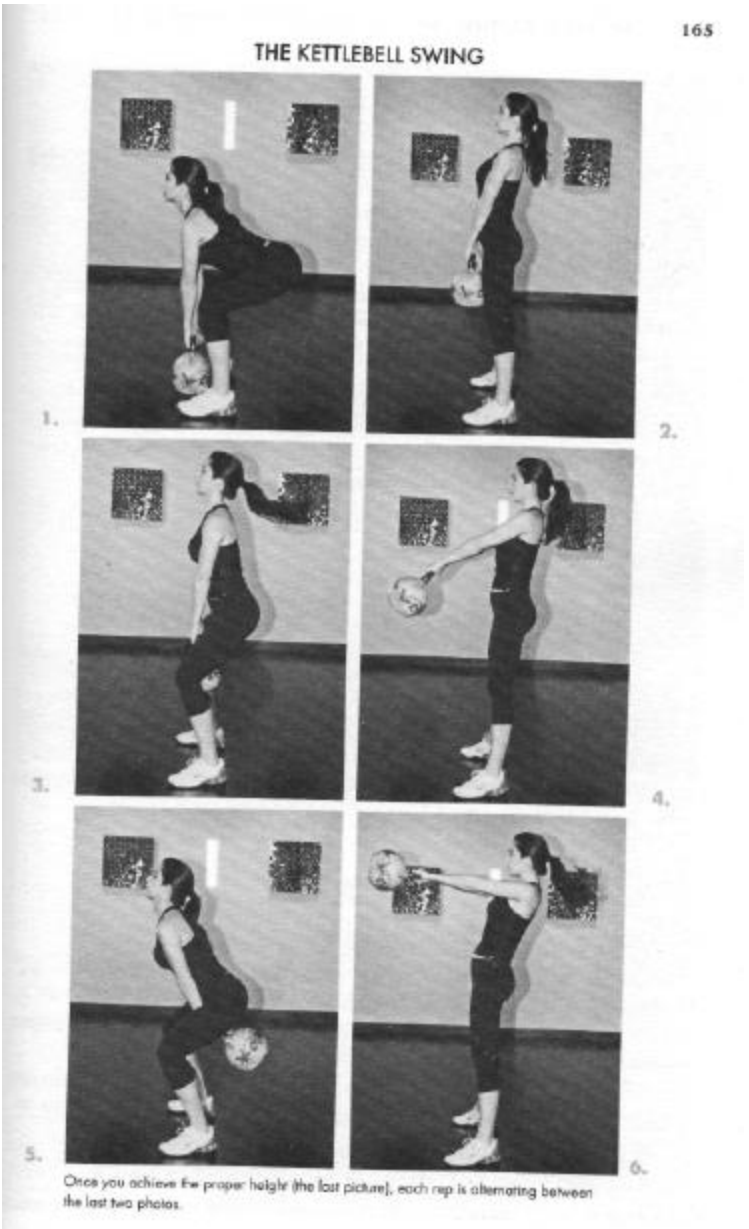
FOOD GROUP	INCLUDE - LOW /SUGAR, LOWER CALORIE FOODS	EXCLUDE/ LIMIT HIGHER FAT/SUGAR, HIGHER CALORIE FOODS
Diary and dairy products	Skim or low fat milk in liquid or powder form. Skim milk powders Low fat buttermilk, natural (plain) low fat yoghurt.	Condensed and evaporated milk. Full cream natural (plain) yoghurt. Milkshakes, Flavoured milk drinks
Fats	Avocado pears, all types of nuts, peanuts, peanut butter (sugar free) olive oil, olives, canola oil, canola margarine, olive oil margarine.	Hard cooking fat, hard (brick margarine) bacon, full fat mayonnaise and cream Coconut oil coconut milk coconut cream, cream, ice cream.
Proteins	Fish: All types - smoked, fresh or frozen (not fried in oil). Poultry: Chicken and turkey without skin - not fried. Legumes: Beans, peas, chick peas and lentils (cooked/canned) Lean Red meat. Lean cold meats. Organ meats: Liver, kidneys (not fried). Lean biltong (fat removed) Eggs: Boiled, poached, omelette, scrambled – limit to two to four eggs per week. Low fat Cheese	Fish: Covered in crumbs, flour and egg or dough. Deep fried in oil Oven baked fish portions - battered or crumbed. Chicken: chicken and turkey with skin. Fried crumbed chicken e.g. Kentucky. Red Meat: Fatty beef, pork, mutton and lamb. Liver spreads, fried liver, liver pate, and liver sausages. Fried eggs. High fat cheeses
Grains, Cereals, Breads	Porridges: Bokomo oats, rolled oats, oat bran, and whole grain breakfast cereals Heavy breads such as - health breads and seed loaves Pasta made from durum wheat Crushed wheat, Popcorn. Baby potatoes, sweet potato – boiled Legumes: dried beans, peas, lentils, chick peas, soya beans	Cereals: Weetbix, Corn flakes, Rice crispies, All baking products made from white bread and white cake flour Baked desserts Low fibre crackers Potatoes Sushi rice, risotto rice
Fruits and Veg.	ALL fresh fruit ALL fresh or frozen vegetables	Fruit canned in syrup .All fruit juices. Vegetables served with hard, margarine, butter or cream.

Addendum 3

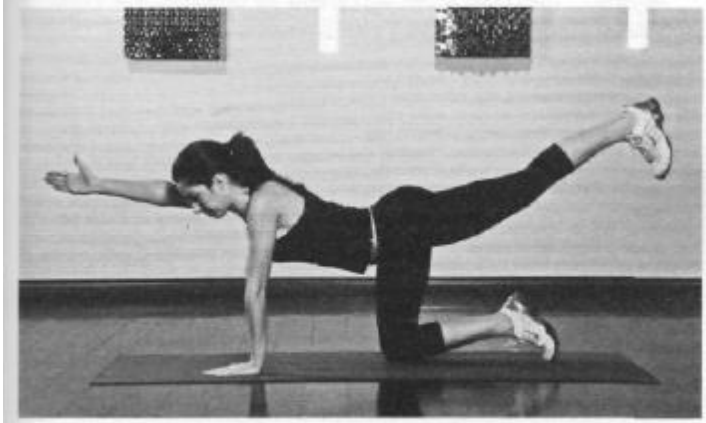
Exercise: From 'The 4-hour body'-Tim Ferris[18]

1) "Kettlebell" (any light weight) swings.
2) Two legged glute activation raises
3) Flying dog

Do three sets of the 3 exercises above over 10-15 minutes four times a week.



Two-legged glute activation raises. Pull the toes up as you drive off of your heels.



Flying dog with right arm and left leg extension. Alternate with left arm and right leg.

Addendum 4 **HREC REF: 651/2014**

Participant Consent Form

Title of Study:

Implementing and evaluating a weight reduction program for Diabetic patients at a Primary Health Care Facility in the Western Cape.

The study has been approved by the Human Research and Ethics committee of UCT (HREC).

I am a postgraduate student from the University of Cape Town and I am conducting a study under the Department of Family Medicine on implementing a weight loss program among diabetics in Mitchells Plain CHC.

The study aims to implement a weight loss program among diabetic patients of the chronic club in Mitchell's Plain.

Patients may partake in the study if:

- Diabetic patients for at least 1 year
- Age 18-65 years
- Overweight or obese
- Ability to attend clinics for follow up
- Taking prescribed medications

Patients may not partake if:

- Pregnant or breast feeding
- Kidney disease
- Liver disease
- GIT disorders
- Severe dyslipidaemia (Total Cholesterol>7.5)
- Currently on another trial or weight loss program

What will happen?

- Potential patients will be asked to join a group meeting.
- Participants will then be randomly assigned to either the low carbohydrate or low fat diet group.
- The eating plan and simple exercises will be explained.
- A following meeting will be arranged to address any questions.
- Consent will be taken for the study.
- Observations and measurements will be taken.
- Bloods will be drawn before the study and again after 12 weeks.
    - A maximum of ten millilitres of bloods will be drawn from the arm before and after the study, using a needle and syringe. This is equivalent to two tablespoons.
    - Complications of drawing blood are rare but may include infection, pain, bleeding, haematomas (bleeding into the skin), bruises and allergic reactions. Any complication arising will be attended to by the research team.
- A final meeting will take place to check understanding and motivation.
- Thereafter the study will commence for a twelve week period.
- Patients will be required to stick to the eating and exercise plan.
- Participants will meet once a month to check measurements and observations.
- During the course of the study, support from the diabetic club will be offered and any questions answered by the doctors running the study.
- Please note that neither diet (low carb or low fat) will guarantee weight loss.

Potential risks:

Research has shown that undertaking the proposed eating plan does not cause any increased risk. If however patients are not coping or are not feeling well they are welcomed to leave the study and support will be provided.

Benefits:

Studies have shown that the diet may lead to improved weight loss, control of blood sugar levels, cholesterol and blood pressure. The study may be used in other facilities to help Diabetic patients with weight loss and diabetes.

Confidentiality:

The results of the study will be used for research and may be published in a medical journal. Names of the participants however will remain anonymous.

Declaration by participant:

By signing below, I …….. agree to take part in a research study entitled

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ..... on (*date*) …….. 2011.

Signature of participant_____ **Signature of witness_____**

Contact details: Dr Isaacs 0834547474, Dr Razack 0824345449, HREC 0214066340